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10/536,617	03/13/2006	Danette Vanessa Choi	A36515-PCT-USA-070013.020	9136

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EXAMINER	
CHAWLA, JYOTI	
ART UNIT	**PAPER NUMBER**
1781	

NOTIFICATION DATE	DELIVERY MODE
04/15/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/536,617	CHOI, DANETTE VANESSA	
	Examiner	Art Unit	
	JYOTI CHAWLA	1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's submission filed on 1/8/2010 has been entered as compliant. Claim 13 has been amended and claims 1-20 are pending and examined in the current application.

Claim Objections

Objection to claim Claim13 made in the previous office action under 37 CFR 1.75 as being a substantial duplicate of claim is withdrawn based on applicant's amendment dated 1/8/2010.

35 USC 1.132 Declaration

Declaration Under 35 USC 1.132 dated 9/23/2009 has been entered. Declaration Dr. Christa Wutschitz (an Internal Medicine practitioner in Geriatric Centre in Austria) states in the declaration that "papaya puree preparation according to the above noted patent application has a surprising and significant efficacy in improving the bowel habit of the patients. This efficacy is not observed in the customary papaya fruit pulp" (Declaration, page 2 step 7).
However, declaration of Dr. Christa Wutschitz and accompanied results have not been found persuasive because the results of the study (Exhibit A, dated 9/23/2009, of record), compare a composition Caracole (C) to a generic uncooked bottled papaya product (P) (see Exhibit A, pages 1-2, fruit preparation) and the effects of the two products in improving the bowel habit of geriatric patients with chronic obstipation (Exhibit A, page 1 study and page 3, conclusion). Currently recited claims are directed to a method of making a papaya puree product and the declaration of Dr. Christa Wutschitz, filed 9/23/2009 is directed to a study addressing a very specific use of a papaya

product for a specific disorder (chronic obstipation) for a very specific group of subjects (geriatric patients).
Thus, the Declaration, as filed, is not commensurate in scope with the invention as claimed, and as such, fails to overcome the outstanding rejections of claims 1-20.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

(A) Claims 1-3 and 5-7, 15-16 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff (US 4089985).

References and rejections are incorporated herein and as cited in the office action mailed on April 2, 2009.

(B) Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff (US 4089985), in view of Swensen (US 5840356).
Wolff has been applied to reject claims 1-3, 5-7, 15-16 and 18-19 under 35 U.S.C. 103(a) above.
References and rejections are incorporated herein and as cited in the office action mailed on April 2, 2009.

(C) Claim 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff (US 4089985) in view of the combination of IDS document by Emma Dawson (The medicinal properties of Papaya), hereinafter Dawson, Chandalia et al (Beneficial Effects of High Dietary Fiber Intake in Patients with Type 2 Diabetes) and Katsuki Imao et al. (Free radical scavenging activity of fermented

papaya preparation and its effect on lipid peroxide level and superoxide dismutase activity in iron-induced epileptic foci of rats).

Wolff has been applied to reject claims 1-3, 5-7, and 15-16, 18-19 under 35 U.S.C. 103(a) above.
References and rejections are incorporated herein and as cited in the office action mailed on April 2, 2009.

Regarding the amended claim 13, adding new limitation that papaya product increases vitality, applicant's attention is directed Katsuki Imao article, as included in the previous office action, Katsuki Imao teaches of an association between antioxidants present in papaya and their positive effect in treatment of free-radical damage related to aging (Page 11, paragraphs 1-3), i.e., anti aging effect of papaya was known at the time of the invention. Vitality or increased energy are characteristics of youth, and the antiaging property would also be responsible for an increase in vitality of an individual. Thus, amended claim 13 is rejected for the same reasons of record as provided in the previous office action for claims 8-14.

(D) Claims 17 and 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff (US 4089985) in view of Nakayama (JP 08056562 A) (English Abstract and machine translation).
Wolff has been applied to reject claims 1-3, 5-7, and 15-16, 16-19 under 35 U.S.C. 103(a) above.

References and rejections are incorporated herein and as cited in the office action mailed on April 2, 2009.

Response to Arguments

Applicant's arguments filed 9/23/2009 have been fully considered but they are not persuasive.

Rejection of claims 1-3 and 5-7, 15-16 and 18-19 under 35 USC 103 over Wolff (US 4089985)

Applicant argues that "Wolff does not disclose or suggest claim 1" (remarks, dated 9/23/09, page 6, third last line). Applicant seems to arrive at this conclusion based on the reasoning that "primary object of Wolff is the production of fruit juice" and "Wolff does not disclose or suggest cooking papaya fruits for at least 30 minutes, or cooling said cooked papaya fruits for a period of at least 30 minutes in an oxygen containing atmosphere" (Remarks, page 7, lines 14-16). Applicant's arguments are not persuasive.

1. Wolff discloses of a method of making papaya product comprising the Carica papaya fruits by blending fresh papaya meat in aqueous medium with or without the addition of water (Column 2, lines 13-28). Regarding the volume of the aqueous medium is at least twice of the water content of the fruits (Column 2, lines (65-68). Applicants claim is also recites "A method for preparing a puree preparation from Carica papaya fruits, … wherein the volume of the aqueous medium is at least twice of the water content of the fruits which includes the limitations as claimed. Thus, Wolff discloses of a papaya puree product as instantly claimed and applicants' argument that "primary object of Wolff is the production of fruit juice" product is different has not been found persuasive. In response to the second argument that "Wolff does not disclose or suggest cooking papaya fruits for at least 30 minutes" (Remarks, page 7, lines 16-18) it is noted that applicant's disclosure does not define the term cooking and that Webster's Dictionary defines the verb "cook" as "to prepare food by the action of heat" (Enclosed evidentiary reference, page 214). Based on the above definition

of cooking Wolff teaches a process which includes the step of cooking of papaya product as Wolff discloses the following:

- "blending of fresh papaya meat for a minimum period of 18 minutes at a very high speed, the high speed blending first raising the temperature of the papaya meat to about 95 F with the blender container covered, secondly holding the temperature of the papaya meat at or above 195ºF (91ºC) for three minutes with the blender container still covered, and finally continuing the high speed blending for a period of five minutes with the blender container uncovered." (Wolff, Column 2, lines 13-28) (Emphasis added).
- "If water is added to the papaya meat for blending, the bitter and unpleasant taste and smell of heretofore known papaya juice products are removed by separating and discarding a foam which forms at the top of the blended product from the remainder of the extract." (Wolff, Column 2, lines 13-28). Also see Column 4, lines 44-46, where Wolff discloses holding the hot blended papaya product at 91 ºC-99 ºC for the duration of the process (Emphasis added).

Thus, Wolff teaches of application of heat in making the papaya product, i.e., cooking. Thus, applicant's argument Wolff not teaching cooking is also not persuasive.

2. Regarding applicant's argument regarding Wolff not disclosing "the time of cooking being less than 30 minutes" (Remarks, page 7, lines 14-16), and "to extend such a period of time to at least 30 minutes is not obvious" (Remarks, page 7, lines 23-24), it is noted that the applicant has not defined any cooking conditions (i.e., temperature range, equipment type, batch size being cooked, etc.) in the recited claims. Further it is noted that claim 1 is being rejected in an obviousness type rejection over Wolff.

Referring back to Webster's Dictionary definition of "cook" as "to prepare food by the action of heat" (Enclosed evidentiary reference, page 214), it has already been established above (response 2) that Wolff teaches of cooking (Column 2,

lines 13-28, Column 2, lines 43 to Column 3, line 5). Some of the cooking times recited by Wolfe include at least 18 minutes for heated blending, hot holding for 3 minutes and hot blending for additional 5 minutes (Column 2, lines 13-28), which is about 26 minutes. Wolff further teaches of pasteurizing temperatures varying between 1 minute to 30 minutes and more (Column 5, lines 1-10). Wolff also discloses of the variable nature of cooking temperatures and times (Column 2-Column 5). Furthermore, it is noted that cooking time and cooking temperature typically have an inverse relationship, i.e., within safe cooking temperature ranges, the time required to heat or cook a product is inversely proportional to the cooking temperature applied. Wolf recognizes the inverse relationship between time and temperature and discloses it in Column 5, in relation to pasteurizing times and temperatures (Column 5, lines 1-10).
It is noted that that the time of heated blending, as disclosed by Wolff can be changed based at least on the factors, such as,

- Initial temperature of papaya used, such as, fresh papaya, frozen or thawed papaya meat (Column 2, lines 63-66)
- temperature of water used "The water can be at room temperature, but in the preferred and tested process, the water at the time of adding it to the papaya meat has been heated to a temperature of approximately 160ºF (71ºC). This will shorten the blending time (Column 3, lines 1-5, and 20-25, Column 4, lines 40-50),
- speed of blending, and
- whether the product is cooked or blended with the lid closed or open
- the amount of product being cooked, and
- the capacity or power of the heating equipment employed.

Also see Wolff's disclosure (Column 2, lines 13-28, Column 2, lines 43 to Column 3, line 5 Column 4, lines 30-50 and Column 5, lines 1-26), where Wolff discloses

of pasteurization and further teaches that minimum time required for pasteurizing at 65ºC is 30 minutes. Thus, it was known to one of ordinary skill in the art at the time of the invention that processing or cooking times vary from one food to another and for the same food based at least on the factors discussed above. It was well within the purview of one of ordinary skill in the art at the time of the invention to vary food cooking and processing time at least based on cooking temperature employed, equipment available to cook the product, amount or batch size of food cooked and desired doneness or consistency of finished product. Therefore, to heat a food product for a specific time (at least for 30 minutes), would have been obvious to one of ordinary skill in the art at the time of the invention. One of ordinary skill would have been motivated to adjust the cooking time based on the other process conditions (as discussed above); at least for the purpose of ensuring that the papaya product is cooked to a desired level. Thus, applicant's argument that invention as claimed is unobvious over Wolff is not persuasive.

3. Regarding applicant's argument regarding Wolff not disclosing “cooling said cooked papaya fruits for a period of at least 30 minutes in an oxygen containing atmosphere” (Remarks, page 7, lines 14-16), it is once again noted that the applicant has not defined any cooling conditions (i.e., temperature range, equipment type, batch size being cooled, any specific proportion of gases etc.) in the recited claims. Further it is noted that claim 1 is being rejected in an obviousness type rejection over Wolff.

Wolff discloses of cooling in an oxygen containing atmosphere, e.g., Wolff states “Immediately after blending, the juice can be treated as follows:

a. placed in cans and sealed, or

b. cooled and placed in cartons similar to liquid milk cartons and maintained in a chilled condition for sale or use, or

c. placed in glass containers and maintained at room temperature or chilled, or

d. if the blended papaya meat into which no water has been added is placed in cans, sealed and frozen, a superior frozen concentrate results."(column 3, lines 63 to Column 4, line 8).Thus cooling papaya products was disclosed by Wolff. Regarding the time for cooling, it is noted that cooling time, as disclosed by Wolff may be varied based at least on the factors, such as,

- final temperature of papaya desired, such as, room temperature papaya, frozen or refrigerated papaya product.
- packaging method and temperature used such as canning requires the product at a different packing temperature, as compared to freezing. speed of blending,
- The final form in which the product is marketed, such as, pureed or frozen or dehydrated or granulated etc,
- method and equipment used for cooling, stirred at room temperature or stirred in a container which is in ice bath, or refrigerator, and
- the amount of product being cooled.

Also see Wolff's disclosure (Column 3, lines 60 to Column 4, lines 10), where Wolff discloses of various methods of packaging the cooked papaya product. Thus, cooling cooked fruit and vegetable products (such as, jams, jellies, preserves and purees) was well known to one of ordinary skill in the art at the time of the invention. Given that cooling time is the only process limitation recited in the claims and that process conditions like cooling conditions, i.e., stirring or agitation etc., which are routinely determinable by one of ordinary skill in the art, based on the final product temperature desired, equipment used for cooling or packaging or both, the batch size being cooled, etc. it would have been well within the purview of one of ordinary skill in the art to modify the cooling time of a cooked product at least in order to achieve desired product temperature. Therefore, to cool a food product for a specific time (at least for 30 minutes as recited), would have been a matter of routine determination for one of ordinary skill in the art at the time of the invention. One of ordinary skill would have been

motivated to adjust the cooling time at least based on the initial temperature of cooked papaya product, the type of equipment or container and the method of cooling employed (e.g., stirring or putting in a wide mouth pot will cool a hot product faster than no stirring or a long and narrow pot) and based on the desired final temperature of the cooled product.
Thus, applicant's argument that limitation of cooling time as recited in the invention is unobvious over Wolff is also not persuasive.

Further, attention is invited to *In re Levin*, 84 USPQ 232 and the cases cited therein, which are considered in point in fact situation of the instant case. At page 234, the Court stated as follows:
This court has taken the position that new recipes or formulas for cooking food which involve the addition or elimination of common ingredients, or for treating them in ways which differ from the former practice, do not amount to invention, merely because it is not disclosed that, in the constantly developing art of preparing food, no one else ever did the particular thing upon which the applicant asserts his right to a patent. In all such cases, there is nothing patentable unless the applicant by a proper showing further establishes a coaction or cooperative relationship between the selected ingredients, which produces a new, unexpected and useful function. In re Benjamin D. White, 17 C.C.P.A. (Patents) 956, 39 F.2d 974, 5 USPQ 267; In re Mason et al., 33 C.C.P.A. (Patents) 1144, 156 F.2d 189, 70 USPQ 221.

4. Applicant's assertion that "the short period of exposure of high temperature for preparing a papaya product as disclosed in Wolff should be more appropriately viewed as Wolff's recognition of heat sensitivity of papaya and an effort to limit the supposedly negative effects caused by exposure to high temperature." (Remarks, page 7, lines 27-30) (emphasis added) are not persuasive. The above assertions are applicant's own assumptions which are unsubstantiated as Wolff does not disclose papain and its temperature sensitivity. Therefore, applicant's arguments fail to comply with 37 CFR 1.111(b)

because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

5. Regarding applicant's remark that "a person skilled in the art would not be motivated to cook papaya fruits for such an extended period of time because it is well known in the art that papain, which is present the papaya fruit is responsible for its beneficial effects, is temperature sensitive. An extended heating period would expectedly destroy these beneficial effects." (Remarks, page 7, lines 24-27). In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e. papain and its temperature sensitivity) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Rejection of claims 4, 8-14, 17 and 20 under 35 USC 103 over Wolff (US 4089985)

Applicants' remarks regarding rejections of claim 4 over Wolff in view of Swensen (Page 8, Paragraph marked (B)), claim 8-14 over Wolff in view of Dawson, Chandalia and Imao (Page 8, Paragraph marked (C)), and claims 17-20 over Wolff in view of Nakayama (Page 9, Paragraph marked (D)) have been considered but they are the same and addressed to Wolff not teaching the invention as recited in claim 1. The remarks regarding Wolff have been addressed above in answers 1-4 of rejection under 35 USC 103 over Wolff.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTI CHAWLA whose telephone number is (571)272-8212. The examiner can normally be reached on 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JC/
Examiner
Art Unit 1781

/Keith D. Hendricks/
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